UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/881,475	06/14/2001	H. Ralph Snodgrass	441472000400	7883

25226 7590 10/25/2002

MORRISON & FOERSTER LLP
755 PAGE MILL RD
PALO ALTO, CA 94304-1018

EXAMINER
SULLIVAN, DANIEL M

ART UNIT	PAPER NUMBER
1636	9

DATE MAILED: 10/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/881,475	Applicant(s) SNODGRASS, H. RALPH	
	Examin r Daniel M Sullivan	Art Unit 1636	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *19,20 and 34-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 21-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4-6* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

This is a First Office Action on the merits of the application filed 14 June 2001 claiming benefit of U.S. Provisional application 60/211,608 filed 14 June 2000. This Office Action is a response to the "Response to Restriction Requirement" filed 22 November 2002 (Paper No. 10) in reply to the Restriction Requirement mailed 20 September 2002 (Paper No. 8).

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-6, 10-18 and 21-33) in Paper No. 10 is acknowledged. Applicant argues persuasively for rejoinder of Groups II and III with the elected Group I. Claims 1-18 and 21-33 will be examined over their full scope. Applicant did not argue for rejoinder of Groups IV-VI with Groups I-III. Therefore, election of rejoined Groups I-III is considered to be without traverse.

Claims 19, 20 and 34-41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention, there being no allowable generic or linking claim.

Claim Rejections - 35 USC § 112

Claims 2-18 and 21-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2, 11-13, 16-23, 26-28 and 31-33 are indefinite in their recitation of "a chemical composition having predetermined toxicities". Claims 3-10, 14, 15, 24 and 29 are indefinite

insofar as they depend from claims 2, 22 or 23. The claims are indefinite because the definition provided for "a chemical composition having predetermined toxicities" does not clearly set forth the metes and bounds such that the skilled artisan would readily know which compounds are included or excluded from the claimed method. On page 8, the specification defines "toxicity" as any adverse effect of a chemical on a living organism or portion thereof (lines 4-5), and "predetermined toxicity" as meaning, "the type of toxicities and/or certain pharmacodynamic properties of the chemical composition have been determined". First, the definition of "toxicity" is unclear because it ultimately depends upon the undefined phrase "adverse effect". Although the meaning of "adverse effect" would be clear in many instances, such as hepatotoxic effects of ethanol, in many other instances what may be an adverse effect in one context is a positive or therapeutic effect in another context. For example, the therapeutic effect of most chemotherapeutic drugs when used in the treatment of cancer would certainly be considered an adverse or toxic effect in other settings such as tissue culture (i.e. portion of an organism). Should it be assumed that once a compound is found to have an "adverse effect" in some system it reads on the chemical composition of the claims? If so, what are the criteria for exclusion of a chemical compound? As pointed out by applicant, "every chemical, and every drug, has an adverse effect at some concentration" (first paragraph on page 8). Therefore, every chemical and every drug potentially meets the limitation of a chemical having predetermined toxicities. Is the only criterion for inclusion then the subjective knowledge of that adverse effect? The meaning of the phrase "predetermined toxicity" is further complicated by including knowledge of "certain pharmacodynamic properties" as sufficient for predetermined toxicity. As there is no indication

which pharmacodynamic properties are being referred to, the skilled artisan could not possibly know which compounds fall within those having predetermined toxicity and which are excluded.

In the interest of compact prosecution, the claims have been examined on the merits according to the broadest reasonable interpretation of "a chemical composition having predetermined toxicities", which is any bioactive compound.

Claims 22 and 23, and claims 24-33 insofar as they depend form claims 22 and 23, are additionally indefinite in their recitation of "said molecular profiles are created according to claim 1" in the step b). Step b) comprises comparing the molecular profile obtained in a) with a composite library of molecular profiles of chemical compositions having predetermined toxicities. There is, however, no antecedent basis for a library of molecular profiles of compositions having predetermined toxicities in claim 1. Amending claims 22 and 23, such that the molecular profiles are created according to the method of claim 2 would obviate this rejection.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Ji *et al.* (published online 14 April 2000) *J. Bone Mineral Metab.* 18:132-139.

Ji *et al.* teaches a method comprising: a) contacting an isolated population of MSCs with a chemical composition (i.e. bone morphogenetic protein-2); and b) recording alterations in gene

expression (i.e. SAGE analysis) in response to the chemical composition (see especially the first paragraph on page 135). Thus, Ji *et al.* teaches all of the method steps of claims 1 and 5 The method taught by Ji *et al.* is the same as the method set forth in claims 1 and 5; therefore, the claims are anticipated by Ji *et al.*

Claims 1, 2, 7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Church *et al.* (May 1999) *Calc. Tissue Int.* 64:S54.

Church *et al.* teaches a method comprising: a) contacting an isolated population of MSCs with a chemical composition (i.e. fetiun and noggin); and b) recording alterations in protein expression (i.e. alkaline phosphatase expression) in response to the chemical composition. Thus, Church *et al.* teaches all of the method steps of claims 1 and 7. In addition, as Church *et al.* teaches the method wherein responses to two chemical compositions are determined according to step c) of claim 2, the method of Church *et al.* also anticipates the limitations of claim 2. Finally, the MSCs of Church *et al.* are human according to the method of claim 10. The method taught by Church *et al.* is the same as the method set forth in the claims; therefore, the claims are anticipated by Church *et al.*

Claims 1-4, 7, 8 and 10 rejected under 35 U.S.C. 102(a) as being anticipated by Bruder *et al.* (1998) U.S. Patent No. 5,736,396 (made of record in the Information Disclosure Statement filed 20 March 2002).

Bruder *et al.* teaches a method comprising: a) contacting an isolated population of MSCs with a chemical composition (i.e. bone morphogenetic protein, see column 13, line 9; and

interleukin-1α, see especially column 14, line 7 and the first full paragraph in column 26); and b) recording alterations in protein expression (i.e. type II collagen matrix, see especially lines 15-18 in column 13; and various cytokines, see especially Table 7 and the first full paragraph in column 26) in response to the chemical composition. Thus, Bruder *et al.* teaches all of the method steps of claims 1 and 7. In addition, as Bruder *et al.* teaches the method wherein responses to two chemical compositions are determined according to step c) of claim 2, the method of Bruder *et al.* also anticipates the limitations of claim 2. Bruder *et al.* further teaches detection of alterations in protein expression by immunohistochemistry (see especially lines 15-18 in column 13) or sandwich ELISA (see especially the second full paragraph in column 22), which are immunoactivity assays according to claim 8 and which the skilled artisan would understand to comprise a label according to claim 3. Finally, Bruder *et al.* teaches colorimetric detection in the ELISA assay (see especially lines 55-57) according to claim 4 and MSCs that are human according to the method of claim 10. The method taught by Bruder *et al.* is the same as the method set forth in the claims; therefore, the claims are anticipated by Bruder *et al.*

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 703-305-4448. The examiner can normally be reached on Monday through Friday 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 703-305-1998. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-746-9105 for regular communications and 703-746-9105 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

dms
January 28, 2003

JAMES KETTER
PRIMARY EXAMINER